

**REMARKS**

The following sections will discuss, in this order, 1) Amendments to the Claims; and 2) Rejection under 35 USC § 102.

**1) Amendments to the Claims**

For business reasons and without acquiescing to any of Examiner's arguments, Applicant has cancelled Claims 1, 3-6, and 30-32 without prejudice and reserving all rights with respect to these claims, including but not limited to the right to prosecute the same or similar claims in one or more future application.

Claims 25, 28 and 29 are currently amended to correct typographical errors and are not amended in response to any objection or rejection.

**2) Rejection under 35 USC § 102**

Claims 1, 3-6, and 25-32 are pending in the present case. The Examiner has rejected these Claims in an Office Action mailed June 2, 2004. Claims 1, 3-6, and 25-32 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chen TT et al. (J. Immunology 1994; 153:4775-4787) (hereinafter "Chen"). As noted above, Claims 1, 3-6 and 30-32 have been cancelled without prejudice. The following remarks are made with respect to remaining claims 25-29.

**A. Claims 25-29 recite the expression of at least three *different* variable regions.**

Claims 25-29 recite, *inter alia*, using nucleic acid isolated from malignant B-cells to recombinantly express particular combinations of variable regions from the immunoglobulins expressed by the malignant B-cells. In particular, the claims recite the expression of at least 3 different variable regions (see, e.g., Claim 25, part b). The at least three variable regions are recited to comprise: at least one V<sub>H</sub> region and at least two V<sub>L</sub> regions, at least two V<sub>H</sub> regions and at least one V<sub>L</sub> region, or at least two V<sub>H</sub> regions and at least two V<sub>L</sub> regions.

The Examiner has pointed out that that V<sub>H</sub> and V<sub>L</sub> regions from a single immunoglobulin differ from each other by at least one idiotope (Office Action of June 2, 2004 at page 3). The claims specify that the at least two V<sub>L</sub> regions differ by at least one idiotope, and that the at least two V<sub>H</sub> regions differ by at least one idiotope. As such, each of these claims recites the

expression of at least 3 *different* variable regions.

**A single immunoglobulin does not provide at least three different variable regions.**

Whole immunoglobulins (*e.g.*, such as those expressed by B-cells) comprise two identical heavy chains and two identical light chains (see, *e.g.*, the National Cancer Institute web page <http://press2.nci.nih.gov/sciencebehind/immune/immune10.htm>.) A single immunoglobulin will thus have four variable regions (2 heavy chain variable, or V<sub>H</sub> regions and 2 light chain variable, or V<sub>L</sub> regions). The V<sub>H</sub> regions will be identical to each other, and thus the V<sub>H</sub> regions will not differ by any idiotopes. Similarly, the V<sub>L</sub> regions will be identical to each other, and thus the V<sub>L</sub> regions will not differ by any idiotope. Thus, a single immunoglobulin provides only two *different* variable regions - one from the heavy chains and one from the light chains.

**Chen provides variable regions from a single immunoglobulin.**

As previously noted, the composition of Chen comprises a single immunoglobulin, the 38C13 Id. See, *e.g.*, 4776, first sentence of column 1: ". . . we have shown that a fusion between *the* 38C13 tumor Id and GM CSF converts *the* tumor Id into a strong immunogen . . ." (*emphasis added*). Chen further makes clear that the antibody-cytokine fusion disclosed consists of heavy and light chain variable regions of only the 38C13 Id immunoglobulin, stating that "the resulting [chimeric Id] protein is composed of *the* 38C13 heavy chain variable region (V<sub>H</sub>38C) and *the* light chain variable region (V<sub>κ</sub>38C) fused to the human IgG1 heavy chain constant region (C<sub>γ</sub>1) and κ light chain constant region (C<sub>κ</sub>), respectively" (Chen, p4777, column 1, *emphasis added*).

**Chen does not disclose expression of at least three different variable regions**

As noted above, a single immunoglobulin has only two different variable regions. Chen provides variable regions from only a single immunoglobulin. Specifically, Chen discloses one type of V<sub>H</sub> region, *i.e.*, the V<sub>H</sub>38C region (and thus does not provide "at least two V<sub>H</sub> regions"). Similarly, Chen discloses only one type of V<sub>L</sub> region, V<sub>κ</sub>38C (and thus does not provide "at least two V<sub>L</sub> regions"). Chen thus discloses the expression of only two different variable regions.

**Claims 25-29 are not anticipated**

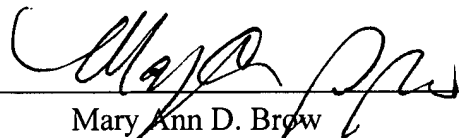
As previously noted, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The present claims recite the expression of at least **three different** variable regions of immunoglobulin molecules. Chen discloses a composition having two different variable regions (from the same immunoglobulin) but fails to teach or suggest a composition comprising three different variable regions of immunoglobulins. Chen does not teach or suggest the desirability of using variable regions from any additional immunoglobulins, such as could provide a third different variable region. As such, Chen reference does not teach each and every element as set forth in Claims 25-29, either expressly or inherently, and thus does not anticipate these claims under 35 U.S.C. § 102(b). Applicant thus respectfully requests that this rejection be removed.

## CONCLUSION

For the reasons set forth above, it is respectfully submitted that all reasons for rejection should be removed and Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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